



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/942,333	08/29/2001	Christopher M. Angelucci	8932-546	7696

69095 7590 10/04/2007
STROOCK & STROOCK & LAVAN, LLP
180 MAIDEN LANE
NEW YORK, NY 10038

EXAMINER

SHAFFER, RICHARD R

ART UNIT	PAPER NUMBER
----------	--------------

3733

MAIL DATE	DELIVERY MODE
-----------	---------------

10/04/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

09/942,333

Applicant(s)

ANGELUCCI ET AL.

Examiner

Richard R. Shaffer

Art Unit

3733

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 August 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-77 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-77 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 August 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 13th, 2007 has been entered.

Drawings

The drawings are objected to because in Figure 2A, reference characters 6A and 6B are orientated with 6B adjacent the vertebral bodies and 6A opposite at the spinous processes. From Figure 1C, this would cause the concave sections to be orientated in the same direction. However, in Figure 2B, the concavities are clearly orientated in a direction perpendicular to the direction required according to the other drawings. Thus, at least one of Figures 1C, 2A and 2B is incorrect. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief

Art Unit: 3733

description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 56 and 57 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 56 recites a ratio of depth D to thickness T of approximately 6:1 and claim 56 recites a ratio of width W to thickness T of approximately 8:1. The specification as originally filed does not support such claim language. Ranges of depth, width and thickness values are supported as originally filed, but one cannot arbitrarily choose values from within a range and compare it to another arbitrarily chosen value and calculate a ratio. For example, depth to thickness could just as easily be 7.5 (taking 1 mm for T and 7.5 mm for D) or 4 (taking 1.5 mm for T and 6.5

Art Unit: 3733

mm for D). Therefore, given the specification, one having ordinary skill in the art would not have found 6:1 to be the optimum or ideal ratio one would desire thereby causing the claim to be new matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 54-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al ("Contact of hydroxyapatite ...", Journal of Orthopaedic Science, 1999) in view of Boyle et al (US Patent 6,277,149) and Ford et al (US Patent 6,511,509).

Hirabayashi et al disclose an implant for maintaining a desired distance between first and second cut ends of a spinous process or lamina. The implant (**Figure 1b, page 265**) comprising a longitudinal axis (axis drawn through the center from left to right in the right picture of **Figure 1b**); a first end (left or right surface in **Figure 1b**); a second end (the opposite surface from the first end); an outer surface (top surface in **Figure 1b**); an inner surface (bottom surface in **Figure 1b**); the outer surface being longer than the inner surface; and the first and second ends are angled at approximately 50-70 degrees with respect to the longitudinal axis of the implant.

Hirabayashi et al fail to disclose the implant being made of allograft, having a bore passing between the first and second ends, the first and second ends being demineralized, the specific values for a wall thickness, depth, and height, channels for

Art Unit: 3733

receiving a surgical instrument, teeth on the first and second ends and a hole formed through the wall to allow the implant to be secured to cut bone.

Boyle et al teach (**Figures 1-21; Column 2, Lines 5-10; Column 2, Lines 40-50; Column 4, Lines 20-32; Column 5, Lines 5-22; and Column 5, Lines 63-67**) allograft implants formed from long bones that include a bore (which corresponds to the intramedullary canal) extending between two roughened ends. The ends (**Column 5, Lines 17-22**) are optionally demineralized in order to improve bone fusion as is well known in the art. Boyle et al further teach that slots and threaded bores are configured to mate with an implant insertion tool in order to facilitate insertion of the implant into the intervertebral space. It would have been obvious to one having ordinary skill in the art the time the invention was made to manufacture the implant of Hirabayashi et al from allograft harvested from long bones in order to avoid necrosis and pain at the iliac crest site as well as to improve bone fusion by utilizing natural bone with a demineralized outer shell, to provide roughened ends to increase fixation against bone, and to provide for slots and openings to allow engagement with an insertion tool to facilitate manipulation of the implant within the body. By manufacturing the bone according to Boyle et al's teaching, the cross-sectional shape would be one of an ellipse, oval or circle.

Ford et al teach (**Figures 1A-2**) a textured bone allograft textured bone (also having an opening therethrough) having various embodiments of teeth extending to a height (**Column 2, Lines 7-15**) including 0.5 mm with the teeth angles (in **Figure 1A**) appearing to be about 45 degrees. It would have been obvious to one having ordinary

Art Unit: 3733

skill in the art at the time the invention was made to consider making the roughened surface of the combination of Hirabayashi et al and Boyle et al as teeth as taught by Ford et al as a matter of mere substitution with predictable results to provide for the ability to help prevent the bone allograft to move relative to the bone.

It would have further been obvious to one having ordinary skill in the art at the time the invention was made to determine all of applicant's claimed ratios and ranges (D:T ratio of 6:1, W:T ratio of 8:1, thickness of 1.25 mm, W between 10 mm and 11.5 mm, D between 6.5 and 7.5 mm, demineralization depth of 2 mm, and an inner side length of 6.0 mm and 10 mm) since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233. In the instant case, Hirabayashi et al was solving the same problem as the instant case with laminoplasty.

Claim 77 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hirabayashi et al in view of Boyle et al and Ford et al (US Patent 6,511,509) and in further view of Kim et al (US Patent 5,980,572).

The combination of Hirabayashi et al, Boyle et al and Ford et al disclose and teach all of the claimed limitations except for an additional hole to allow the implant to be secured to the cut bone. Kim et al teach (**Column 4, Lines 40-45**) that through-holes (**12b and 13b, Figure 1**) allow for a nylon wire to fix the implant to the divided spines (cut bone in applicant's claim). It would have been obvious to one having ordinary skill in the art at the time the invention was made to provide for additional holes to allow a nylon wire to pass through to provide for a secure initial fixation of the implant relative to

Art Unit: 3733

the bone (by pressing surfaces of the implant against bone) for a laminoplasty procedure.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection. Specifically, the new rejections give clear motivation why one of ordinary skill in the art at the time of the invention would have found the claimed invention obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard R. Shaffer whose telephone number is 571-272-8683. The examiner can normally be reached on Monday-Friday (7am-5pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3733

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Richard Shaffer
September 29th, 2007



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER